

Practitioner's Docket No. R00360US (#90568)

CHAPTER II

Preliminary Classification:

Proposed Class: 424/448

Subclass: A61F 13/02

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P., § 601, 7th ed.

**TRANSMITTAL LETTER
TO THE UNITED STATES ELECTED OFFICE (EO/US)**

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO. PCT/EP00/03152	INTERNATIONAL FILING DATE 08 APRIL 2000	PRIORITY DATE CLAIMED 23 APRIL 1999
TITLE OF INVENTION METHOD AND DEVICE FOR LABELING A TWO-DIMENSIONAL POLYMER ADHESIVE SYSTEM, ESPECIALLY A TRANSDERMAL THERAPEUTIC SYSTEM		
APPLICANT(S) BECHER, Frank		

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date October 23, 2001, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EF1703750730US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Sean Mellino

(type or print name of person mailing paper)

Sean Mellino

Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

WARNING: Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8.

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

- I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:
- a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).
 - b. ☒ The U.S. National Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

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2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
<input checked="" type="checkbox"/>	TOTAL CLAIMS	16 - 20 =	---	× \$18.00 =	\$ ---
	INDEPENDENT CLAIMS	3 - 3 =	---	× $\frac{84.00}{78.00}$ =	---
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) $\frac{280.00}{+ \$260.00}$				---
BASIC FEE**	<input type="checkbox"/> U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: <input type="checkbox"/> and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 C.F.R. § 1.492(a)(4)) $\frac{100.00}{\$96.00}$ <input type="checkbox"/> and the above requirements are not met (37 C.F.R. § 1.492(a)(1)) $\frac{710.00}{\$670.00}$				
	<input checked="" type="checkbox"/> U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: <input type="checkbox"/> has been paid (37 C.F.R. § 1.492(a)(2)) $\frac{740.00}{\$690.00}$ <input type="checkbox"/> has not been paid (37 C.F.R. § 1.492(a)(3)) $\frac{870.00}{\$840.00}$ <input checked="" type="checkbox"/> where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. § 1.492(a)(5)) $\frac{890.00}{\$840.00}$				890.00
	Total of above Calculations =				890.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (note 37 C.F.R. § 1.9, 1.27, 1.28)				---
	Subtotal				890.00
	Total National Fee \$				890.00
	Fee for recording the enclosed assignment document \$40.00 (37 C.F.R. § 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				---
TOTAL	Total Fees enclosed \$				890.00

JC13 Rec'd PCT/PTO 23 OCT 2001

*See attached Preliminary Amendment Reducing the Number of Claims.

- i. ☒ ~~CREDIT CARD FORM~~ ~~A check~~ in the amount of \$890.00--to cover the above fees is enclosed.
- ii. ☐ Please charge Account No. _____ in the amount of \$ _____.
A duplicate copy of this sheet is enclosed.

****WARNING:** "To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).

WARNING: If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.

3. ☒ A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

- a. ☒ is transmitted herewith.
- b. ☐ is not required, as the application was filed with the United States Receiving Office.
- c. ☐ has been transmitted
- i. ☐ by the International Bureau.
Date of mailing of the application (from form PCT/1B/308): _____
- ii. ☐ by applicant on _____
Date

4. ☒ A translation of the International application into the English language (35 U.S.C. § 371(c)(2)):

- a. ☒ is transmitted herewith.
- b. ☐ is not required as the application was filed in English.
- c. ☐ was previously transmitted by applicant on _____
Date
- d. ☐ will follow.

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5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

- a. ☐ are transmitted herewith.
- b. ☐ have been transmitted
 - i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1B/308): _____
 - ii. ☐ by applicant on (date) _____
Date
- c. ☒ have not been transmitted as
 - i. ☒ applicant chose not to make amendments under PCT Article 19.
Date of mailing of Search Report (from form PCT/ISA/210): 10 August 2000
 - ii. ☐ the time limit for the submission of amendments has not yet expired.
The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. § 371(c)(3)):

- a. ☐ is transmitted herewith.
- b. ☐ is not required as the amendments were made in the English language.
- c. ☒ has not been transmitted for reasons indicated at point 5(c) above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

- ☒ is transmitted herewith.
- ☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

- a. ☒ is/are transmitted herewith.
- b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

- a. ☒ is transmitted herewith.
- b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115
- a. ☐ was previously submitted by applicant on _____
Date
- b. ☐ is submitted herewith, and such oath or declaration
- i. ☐ is attached to the application.
- ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. § 1.70.
- c. ☒ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):
- a. ☒ is transmitted herewith.
- b. ☐ has been transmitted by the International Bureau.
Date of mailing (from form PCT/IB/308): _____
- c. ☐ is not required, as the application was searched by the United States International Searching Authority.
- d. ☐ will be transmitted promptly upon request.
- e. ☐ has been submitted by applicant on _____
Date
12. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:
- a. ☐ is transmitted herewith.
Also transmitted herewith is/are:
- ☐ Form PTO-1449 (PTO/SB/08A and 08B).
- ☐ Copies of citations listed.
- b. ☒ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).
- c. ☐ was previously submitted by applicant on _____
Date
13. ☐ An assignment document is transmitted herewith for recording.
A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.
- _____

14. ☒ Additional documents:
- a. ☐ Copy of request (PCT/RO/101)
 - b. ☒ International Publication No. WO 00/64684
 - i. ☐ Specification, claims and drawing
 - ii. ☒ Front page only
 - c. ☒ Preliminary amendment (37 C.F.R. § 1.121)
 - d. ☒ Other
Written Opinion (PCT/IPEA/408); Response to Written
Opinion (dated 09.04.2001 - in German); Transmittal for
IPER (PCT/IPEA/416); Credit Card Payment Form
15. ☒ The above checked items are being transmitted
- a. ☒ before 30 months from any claimed priority date.
 - b. ☐ after 30 months.
16. ☐ Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on _____, namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 08-2441

☒ 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.

☒ 37 C.F.R. § 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☒ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

Sean Mellino

SIGNATURE OF PRACTITIONER

Sean Mellino

Reg. No.: 48,817

Tel. No.: (216) 771-3800

(type or print name of practitioner)

D. PETER HOCHBERG CO., L.P.A.
1940 E. 6TH STREET - 6TH FLOOR

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P.O. Address

CLEVELAND, OH 44114-2294

(Transmittal Letter to the United States Elected Office (EO/US) [13-18]—page 8 of 8)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Frank Becher
Serial No. : N/A
Filing Date : Herewith
Title : Process and Device for Inscription of a
Sheet-Like adhesive System of a
Polymer, Especially of a Transdermal
Therapeutic System (as amended herein)
Group Art Unit : N/A
Examiner : N/A
Attorney Docket : RO0360US (#90568)

Box PCT
Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-referenced application as follows:

IN THE TITLE:

Please amend the title to read as follows:

Process and Device for Inscription of a Sheet-Like adhesive System of a
Polymer,
Especially of a Transdermal Therapeutic System

IN THE CLAIMS:

Please cancel claims 1-12 and replace with the following new claims:

--13. (New) A process for inscription of a sheet-like adhesive system made of a
polymer having an adhesive-free side, the system including at least one ingredient-
containing layer, a material layer to be inscribed; an information layer overlying said

material layer to be inscribed and a backing layer impermeable to ingredients or water vapor, and using a movably guided laser beam emission device, said process comprising:

placing the adhesive in a support position;

guiding the laser emission device to emit the laser beam onto the device by a program of a manually operable central control unit; and

controlling the intensity and penetration depth of the laser beam according to the material properties of the system in such a way that the laser beam does not penetrate far enough to reach one of the at least one ingredient-containing layer and preventing a detrimental influence on the ingredients contained in the system.

14. (New) The process according to claim 13 wherein the sheet-like adhesive system -is an active agent-containing therapeutic system.
15. (New) The process according to claim 14 wherein the active-agent containing therapeutic system is in the form of a plaster.
16. (New) The process according to claim 13 wherein said detrimental influence is heat generated by said guided laser beam.
17. (New) The process according to claim 13 wherein said detrimental influence is a perforation of said backing layer.
18. (New) The process according to claim 13 and further including covering the layer to be inscribed with an overlying layer having information in the form of characters or signs thereon, said overlying layer being a color layer which disintegrates at a moderate laser irradiation level, applying the moderate laser irradiation level to disintegrate the color level and inscribing the laser-exposed information in the form of characters or signs onto the underlying layer to be inscribed.

19. (New) The process according to claim 13 wherein at least one pigment-containing layer is under the layer to be inscribed and each of the at least one pigment-containing layers disintegrates at a moderate laser irradiation level, and the process further includes applying the moderate laser irradiation level to disintegrate the at least one pigment containing layer while applying the laser-exposed characters onto the underlying pigmented layer.
20. (New) The process according to claim 13 wherein the overlying information layer has a conspicuous color relative to the layer to be inscribed.
21. (New) The process according to claim 13 and further including setting the intensity of the effect of the laser beam to particular parameters, and setting the parameters determining the intensity of the effect of the laser beam on the layer to be inscribed to modify only the uppermost layers of the system.
22. (New) The process according to claim 13 and further including guiding by electromagnetic control the movably guided laser beam to amend, delete or input at any point the information being inscribed by the program of the manually operable central control unit.
23. (New) The process according to claim 22 wherein the central control unit includes a keyboard.
24. (New) A process according to claim 22 and further including transferring the data generated by other production steps to the program of the central control unit.
25. (New) A process according to claim 13 wherein the process further includes a method to produce single-colored or multi-colored pattern of characters or signs comprising applying at least two overlying pigmented layers to the layer to be inscribed, and further including disintegrating the at least two pigmented layers by

accurate control of the penetration depth of the laser beam to visualize the at least two underlying pigmented color layers.

26. (New) A device for the inscription of a sheet-like adhesive system comprising a laser appliance cooperating with a means for the control of the laser beam as to its direction and irradiation intensity as determined by a manually operable control unit which is provided with a data memory and a data processor, characterized in that the control unit has superimposed thereon a keyboard with a converter for immediate digital input of characters or other signs or corresponding data records.

27. (New) A device according to claim 26 and further including transferring the data generated by other production steps alternately or simultaneously to a program of the control unit for control.

28. (New) A device for inscription of a sheet-like adhesive system comprising a laser appliance cooperating with a means for the control of a laser beam as to its direction and irradiation intensity as determined by a control unit which is provided with a data memory and a data processor, characterized in that the data generated by other production steps are transferred to control a program of the control unit.--


REMARKS

The English translation of the specification submitted herewith is an accurate translation of the original specification.

The pending claims in PCT/EP00/03152 have been canceled and replaced with a new set of claims set to conform to U.S. practice for entry into National Phase. No

new matter has been added. Accordingly, prosecution on the merits hereof is respectfully requested.

Respectfully submitted,


Sean Mellino
Reg. No. 48,817

D. Peter Hochberg Co., L.P.A.
1940 E.6th Street – 6th Floor
Cleveland, OH 44114-2294
(216) 771-3800

SFM/sfm

EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that the foregoing Preliminary Amendment and any document(s) referred to as attached hereto is being deposited with the United States Postal Service on the date indicated below in an envelope as "Express Mail Post Office to Addressee" service mailing Label Number EF170375073US addressed. BOX PCT, Commissioner for Patents, Washington, D.C., 20231.

Date: October 23, 2001


Sean F. Mellino

LTS 1998/042 WO

Method and Device for Labeling a Two-Dimensional Polymer
Adhesive System, Especially a Transdermal
Therapeutic System

The invention relates to a process for inscription of a sheet-like adhesive system of a polymer, preferably on the side averted from the adhesive side, with information, e.g. indications to identify the system as such or the object to which the system is to be adhered.

There are many different types of sheet-like adhesive systems of a polymer, such as

- adhesive films, e.g. (possibly transparent) adhesive films for identification marking of switchboards and technical appliances,
- technical adhesive strips or tapes,
- fixing plasters (e.g. for fixation of bandages) for application on the skin,
- wound plasters with wound dressings,
- plasters with active agents such as antirheumatic plasters for topical application of active agents to the skin,
- plasters with active agents for systemic application of active agents onto and through the skin, so-called transdermal therapeutic systems (TTSS),
- plant protection plasters comprising active agents for application of plant protection agents.

With sheet-like adhesive systems there is a need to apply information relating, for example, to their properties, their use, their intolerances or incompatibilities, storage conditions and useful life-span, as well as, possibly, information relating to special properties of the object to which the system is to be stuck (label function),

- the printing ink requires time to dry

- Furthermore, ink jet printers are known, to which in part the same disadvantages but also other disadvantages apply:

- It is also known to apply an inscription technique by means of a movably guided laser beam utilising toners, wherein the toner is thermally fixed, for example, on paper; however, toner adheres only insufficiently to most polymer supports.

Furthermore, it is known to employ an inscription technique by means of a movably guided laser beam, for example, on a metal substrate, especially on a light metal substrate. Here, by way of punctually extremely intensive light emission, the laser beam produces temperatures so high that the crystal structure of the metal is superficially changed such that the metal adopts a different colour. Laser beam appliances have also been used, for example, to apply letters or signs on electronic cables which are covered by a comparatively thick layer of plastic or rubber. Known are laser appliances for marking of cables with information by way of in-line laser marking which work with a freely programmable matrix system, this allows representation of almost any characters and symbols. Rates of up to 450 m/min are common in these lasers.

Owing to possible harmful effects of the laser beam on an inscription substrate of a thin polymer that is provided with ingredients such as adhesives, plasticizers, enhancers and active agents, and to the penetration depth of the beam, toner-free laser inscription on thin, sheet-like adhesive systems has heretofore not been made use of. With all adhesives there are fears that under the influence of high temperatures the adhesive mass will react with residual monomers; and with hot-melt adhesives it is feared that their adhesive power will be diminished under action of heat.

Starting from the above, in a process of the kind mentioned in the introductory portion of Claim 1 it is the object of the invention to provide operating parameters or implementing conditions for the inscription of adhesive systems of polymers with the aid of a movably guided laser beam, which operating parameters or implementing conditions are suited to securely prevent a detrimental change in the sheet-like adhesive system caused, for example, by a perforation

eliminating the impermeability of the backing layer, negative changes in the backing layer and in ingredients such as adhesives, or, respectively, a thermal change in the additives such as plasticizers and enhancers or in the active agent.

To achieve this object in a process of the kind mentioned in the introductory part of Claim 1, the present invention proposes to perform the inscription with the aid of a movably guided laser beam in such a manner that a detrimental influence on the ingredients such as adhesives, additives such as softeners, enhancers, or active substance contained in the adhesive system, due, in particular, to the heat generated by the laser beam or to perforation of the backing layer, which is impermeable to ingredients such as adhesive, active agent and/or water vapour, is avoided and that to this end the intensity and penetration depth of the laser beam be adjusted, in accordance with the properties of the material of the sheet-like adhesive system, in such a way that the laser beam does not penetrate far enough to reach components such as, for example, an additive- or active agent-containing layer, of the sheet-like adhesive system/plaster, and, in particular, does not reach the active substance reservoir.

The inscription can also be carried out by negative signs, that is by working letters and signs from surfaces which are not affected by the laser beam.

Advantageously, it is further provided that the inscription is performed immediately following the manufacture of the broad backing layer film webs, or in any later manufacturing step - after coating, adding other films by laminating, cutting into narrow rolls, or after separating as the last operational step.

Here it is possible also to cover any desired working widths, i.e. including broad webs of adhesive films, by

A further embodiment of the process according to the invention which is essential to the invention provides that the laser beam is guided by means of electromagnetic control such that it is possible at any time to input or amend individual signs or groups of characters according to

a programme of a central control unit, and, in particular, to input characters by hand via an EDP-controlled typewriter-like keyset ("keyboard").

With the present invention it is for the first time possible to manually input characters and data records in a sheet-like adhesive system/plaster as with a typewriter, which is of particular advantage.

Finally, the process according to the invention provides that to produce a single-coloured or multicoloured pattern of characters or signs, at least two pigmented layers are disposed on the inscription substrate layer so as to overly one another, and that these are disintegrated by extremely accurate penetration depth control of the laser beam in such a way that the respective underlying pigmented colour layer is visible.

This manner of inscription could also be carried out on an appropriate polymer background. Altogether, the process according to the invention overcomes the attitude hitherto held by the experts that a sheet-like adhesive system/plaster can not be utilized for inscription by means of a laser beam because of the sensitivity of the ingredients such as adhesives, additives and active agents, and the depth action of a laser beam.

This prejudice is out-dated by the invention since through the invention it has now become possible to control the laser beam, respectively its intensity, in such a way that it affects only the uppermost material layers and apart from that has no effect on the remaining substrate.

The process according to the invention now dispels the reservations against laser inscription of sheet-like adhesive systems, which have hitherto stood in the way of utilizing laser inscription in this sector. It emerges that laser inscription is useful, accurate, can be modified

- is controlled either by data from other production steps or
- by the fact that a keyboard with a converter for immediate manual digital input of characters or

1. Process for inscription of a sheet-like adhesive system of a polymer, preferably on the adhesive-free side thereof, with information, [characterized in that the inscription is carried out with the aid of] a movably guided laser beam in such a manner that a detrimental influence on the ingredients contained in the system, in particular by heat generated by the laser beam or by detrimental perforation of a backing layer impermeable to ingredients or water vapour, is avoided, and that to this end the intensity and penetration depth of the laser beam is adjusted according to the material properties of the system in such a way that the laser beam does not penetrate far enough to reach an ingredient-containing layer of the system.

2. Process according to Claim 1, characterized in that as the sheet-like adhesive system an active agent-containing therapeutic system in the form of a plaster is utilised.

3. Process according to Claim 1 or 2, characterized in that the material layer to be inscribed is covered with an overlying layer, e.g. a colour layer printed thereon, which is selected such that it disintegrates already at comparatively moderate laser irradiation and in the process visualises the lased characters on the background of the underlying material layer.

4. Process according to Claim 1 or 2, characterized in that under the material layer to be inscribed there is at least one pigment-containing layer, each of the layers being selected such that it disintegrates already at comparatively moderate laser irradiation and in the process visualises the lased characters on the background of the underlying pigmented layer.

9. Process according to one or more of Claims 1 to 6, characterized in that to produce a single-coloured or multicoloured pattern of characters or signs, at least two pigmented layers are applied to the inscription substrate layer so as to overly one another, and that these are disintegrated by accurate control of the penetration depth

of the laser beam such that the respective underlying pigmented colour layer is visualised.

10. Device for inscription of a sheet-like adhesive system, in particular for carrying out the process according to Claims 1 to 9, comprising a laser appliance co-operating with means for the control of the laser beam as to its direction and irradiation intensity as determined by a control unit which is provided with a data memory and a data processor, characterized in that the control unit has superimposed thereon a keyboard with a converter for immediate digital input, by hand, of characters or other signs or corresponding data records.

11. Device according to Claim 10, characterized in that data generated by other production steps are transferred alternately or simultaneously to the programme of the control unit for control.

12. Device for inscription of a sheet-like adhesive system, in particular for carrying out the process according to Claims 1 to 9, comprising a laser appliance co-operating with means for the control of the laser beam as to its direction and irradiation intensity as determined by a control unit which is provided with a data memory and a data processor, characterized in that data generated by other production steps are transferred to control the programme of the control unit.

Attorney Docket No. R00360US (# 90568)

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL,
DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

- () original
() design

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check any of next two items and check appropriate one of last three items.

- (X) national stage of PCT
() supplemental

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional
☐ continuation
☐ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

Method and devise for labeling a two-dimensional polymer adhesive system, especially a transdermal therapeutic system.

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b), or (c))

- (a) ☐ is attached hereto.
- (b) ☐ was filed on _____ as ☐ Serial No. _____ or
☐ Express Mail No. _____, as Serial No. not yet known
and was amended on _____ (if applicable).

- (c) (X) was described and claimed in PCT International Application No. PCT/EP 00/03152 filed on April 8th, 2000 and as amended under PCT Article 19 on (if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations. Sec. 1.56(a).

- () In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) () no such applications have been filed.
(e) (X) such applications have been filed as follows

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NO.	DATE OF FILING (month,day,year)	PRIORITY CLAIMED UNDER 37 USC 119
DE	199 18 473.9	April 23, 1999	(X) YES NO ()
			() YES NO ()
			() YES NO ()

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

POWER OF ATTORNEY

(3)

As a named inventor, I hereby appoint D. Peter Hochberg, Reg. No. 24,603, Katherine R. Vieyra, Reg. No. 47,155, and William H. Holt, Reg. No. 20,766, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

1-50 Full name of sole or first inventor: Frank Becher

Becher

Inventor's signature

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DEX

**CHECK PROPER BOX(ES) IF ANY OF THE FOLLOWING ADDED PAGE(S)
FORM A PART OF THIS DECLARATION**

- () Signature for third and subsequent joint inventors. Number of pages added _____ .
- () Signature by administrator(trix), executor(trix) or legal representative of deceased or incapacitated inventor. Number of pages added _____ .
- () Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. Number of pages added _____ .

- () Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (CIP) application.
- () Number of pages added _____ .

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item.

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